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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/522,334	03/09/2000	Ry Wagner	4257-0018.30	3299
23500	7590	10/08/2004	EXAMINER	
PATENT DEPT EXELIXIS, INC. 170 HARBOR WAY P.O. BOX 511 SOUTH SAN FRANCISCO, CA 94083-0511			KRUSE, DAVID H	
			ART UNIT	PAPER NUMBER
			1638	

DATE MAILED: 10/08/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/522,334

Applicant(s)

WAGNER ET AL.

Examiner

David H Kruse

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 January 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2-10, 16, 17 and 19-23 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 2-10, 16, 17 and 19-23 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date: _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date: _____ | 6) <input type="checkbox"/> Other: _____ |

STATUS OF THE APPLICATION

1. This Office action is in response to the Amendment and Remarks filed 5 January 2004.
2. The objection to the drawings is withdrawn in view of Applicant's amendment to the specification.
3. The Objection to claim 20 is withdrawn in view of Applicant's amendment.
4. Those rejections not specifically addressed in this Office action are withdrawn in view of Applicant's amendments to the claims.
5. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Objections

6. Claims 2 and 16 are objected to because of the following informalities:

At claim 2, line 4, "and" should be inserted at the end of the line.

At claim 16, line 3, a "," should be inserted after "vitamins".

Appropriate correction is required.

Claim Rejections - 35 USC § 112

7. Claims 21 and 22 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 21 and 22 are indefinite because Applicant does not teach introduction of *Agrobacterium tumefaciens* into a tomato tissue. One of skill in the art would recognize that *Agrobacterium tumefaciens* transfers the Ti plasmid into the plant cell from the plant

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cell's exterior through pili, but does not enter the plant cell. In addition the term "derived" renders the claim indefinite because it is unclear what the metes and bounds of this limitation are, it is suggested that the term be deleted from the claims.

8. Claims 2 and 19 are rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Applicant's amendment to claim 19 is noted.

Applicant claims a method using a heterologous gene construct identified in the method of claim 20.

Applicant describes a 3.7kb and 4.5kb genomic insert fragment rescued using said method of claim 20.

Applicant does not describe the function of the identified fragments, nor does Applicant describe other "genes" that produce a desired trait.

Hence, it is unclear that Applicant was in possession of the invention as broadly claimed.

See *Amgen inc. v Chagai Pharmaceutical co.*, 18 USPQ 2d 1016 (Fed. Cir. 1991), which teaches that the conception of a chemical compound requires the inventor to be able to define the compound so as to distinguish it from other materials, and to describe how to obtain it rather than simply defining it solely by its principle biological property; thus, when an inventor of a gene, which is a chemical compound albeit a complex one, is unable to envision detailed constitution of the gene so as to distinguish

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it from other materials, as well as a method of obtaining it, the conception is not achieved until a reduction to practice has occurred, and until after the gene has been isolated. See also, MPEP § 2163 which states that the claimed invention as a whole may not be adequately described where an invention is described solely in terms of a method of its making coupled with its function and there is no described or art-recognized correlation or relationship between the structure of the invention and its function. A biomolecule sequence described only by a functional characteristic, without any known or disclosed correlation between that function and the structure of the sequence, normally is not a sufficient identifying characteristic for written description purposes, even when accompanied by a method of obtaining the claimed sequence. The instant claims lack adequate written description because the method they are directed to requires products not described by Applicant. A method is not described if products used in the method are not described. See 64 Fed. Reg. 71427, 71428 (1999), comment No. 4.

Claim Rejections - 35 USC § 102

9. Claims 8, 9, 10, 17 and 20 remain rejected under 35 U.S.C. § 102(b) as being anticipated by Jones *et al* (1994, Science 266:789-793) taken with the evidence of Jones *et al* (1992, Proceedings of the Royal Society of Edinburgh, 99B (3/4) pages 107-119). This rejection is repeated for the reason of record as set forth in the last Office action mailed 3 July 2002. Applicant's arguments filed 5 January 2004 have been fully considered but they are not persuasive.

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Applicant argues that the term "enhancer" has a well-defined meaning within the art of transgenic plants and refers to a DNA regulatory sequence that influences transcription of a structural gene, and that Jones et al. (1994) do not disclose a plant cell expression vector that comprises an enhancer. Accordingly, the rejection should be withdrawn (page 7, 2nd paragraph of the Remarks). This argument is not found to be persuasive because the maize transposon *Activator* (Ac) acts as an enhancer of gene expression and thus meets the limitation of the claims.

Claim Rejections - 35 USC § 103

10. Claims 2-10, 16, 17 and 19-23 remain rejected under 35 U.S.C. § 103(a) as being unpatentable over Walden *et al* 1994 (Plant Molecular Biology 26:1521-1528) in view of Jones *et al* 1992 (Proceedings of the Royal Society of Edinburgh, 99B (3/4) pages 107-119). This rejection is repeated for the reason of record as set forth in the last Office action mailed 3 July 2002. Applicant's arguments filed 5 January 2004 have been fully considered but they are not persuasive.

Applicant argues that the various publications by the Walden *et al* lab relating to these results were subsequently retracted, referring to Applicant's response filed August 6, 2001(page 7, 4th paragraph of the Remarks). This argument is not found to be persuasive because said retraction was directed to the function of the identified gene, and does not obviate the teachings of Walden *et al* as it is directed to the use of promoter tagging to identify desired trait genes.

Applicant argues that given the inadequacies of the Walden *et al* reference, one skilled in the art would not have had a reasonable expectation of success from the

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combined teachings of Walden *et al* and Jones *et al* that activation tagging would be successful in tomato (page 7, 5th paragraph of the Remarks). This argument is not found to be persuasive because Jones *et al* teaches that one of ordinary skill in the art can use methods in tomato of activation tagging to identify desired trait genes. Walden *et al* teaches the method of promoter tagging to identify desired trait genes in plants, and it would have been obvious to one of ordinary skill in the art at the time of Applicant's invention to modify the teachings of Walden *et al* to use promoter tagging in tomato as taught by Jones *et al* to identify desired trait genes. Even though Walden *et al* subsequently states that the identified desired trait gene did not function as asserted, Walden *et al* does not teach away from the instant invention in any way.

Applicant argues that unexpected results may be demonstrated to rebut a *prima facie* case of obviousness, in the instant case, a *prima facie* case of obviousness against claims 21 and 22 has not yet been established because the Examiner has not shown how the prior art teaches the features of these claims (page 8, 1st paragraph of the Remarks). The transformation of hypocotyls or shoot tip tissue of tomato would not have lead to a teaching of unexpected results because *Agrobacterium* transformation of such tissue would have been obvious to one of ordinary skill in the art at the time of the instant invention. If Applicant can successfully argue that transformation of such tissue would not have been obvious in practicing the method of the instant claims, then these limitations should be incorporated into independent claim 20. See *In re Lindner*, 173 USPQ 356 (CCPA 1972) and *In re Grasselli*, 218 USPQ 769 (Fed. Cir. 1983) which

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teach that the evidence of nonobviousness should be commensurate with the scope of the claims.

Conclusion

11. This Office action is non-final in view of the new grounds of rejection put forth not previously presented in the last Office action.

12. No claims are allowed.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to David H. Kruse, Ph.D. whose telephone number is (571) 272-0799. The examiner can normally be reached on Monday to Friday from 8:00 a.m. to 4:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Amy Nelson can be reached at (571) 272-0804. The fax telephone number for this Group is (703) 872-9306 Before Final or (703) 872-9307 After Final.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group Receptionist whose telephone number is (571) 272-0547.


DAVID H. KRUSE, PH.D.
PATENT EXAMINER

David H. Kruse, Ph.D.
6 October 2004

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14. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

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